

MAY 25 2000



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

#17

David T. Read
Acting Director Regulatory Policy Staff, CDER
Food and Drug Administration
1451 Rockville Pike, HFD-7
Rockville, MD 20852

Dear Mr. Read:

The attached application for patent term extension of U.S. Patent No. 5,360,897 was filed on April 14, 2000, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, Prevnair™ (Diphtheria CRM₁₉₇ protein), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product, or the method of use of manufacturing such a product, which has been subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.

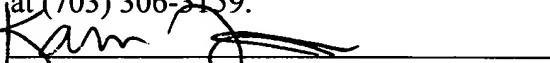
Any correspondence, especially any change of address from applicant, with respect to this matter should be addressed as follows:

By mail: Commissioner for Patents
 Box Patent Ext.
 Washington, D.C. 20231

By hand: Crystal Plaza Four, Suite 3C23
 2201 South Clark Place
 Arlington, VA 22202

By FAX: (703) 308-6916 or (703)941-8711
 Attn: Karin Tyson

Telephone inquiries regarding this communication should be directed to the undersigned at (703) 306-3159.


Karin Tyson, Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Estelle J. Tsevdos
 Kenyon & Kenyon
 One Broadway
 New York NY 10004